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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,825	07/21/2003	Gudmundur G. Haraldsson	CONLINCO-08305	5723
23535 7590 06/04/2007 MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			EXAMINER EBRAHIM, NABILA G	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 06/04/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/623,825

Applicant(s)

HARALDSSON ET AL.

Examiner

Nabila G. Ebrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/15/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of claims Group I, claims 12-13, in the reply file on 2/15/07 is acknowledged.
2. Applicant cancelled claims 14-21.

### ***Priority***

Applicants are not entitled to the priority dates for the claimed subject matter because the applicants were not in possession of the claimed invention as of the filing dates. None of such applications discloses a content of 8,10 octadecadienoic acid and 11,13 octadecadienoic acid isomers of less than 2% in the aggregate. For example 09/160416 discloses less than 5% of 8,10-octadecadienoic acid and 11,13 octadecadienoic acid isomers. Since there is no support for this subject matter in the parent case the application is considered a CIP of 09/160416. Consequently, Applicant is denied the priority filing date of 9/25/1998. It is also noted that Applicant has filed a preliminary amendment to the claims on the same day of the filing date and therefore the filing date of 7/21/2003 is the considered filing date and no priority is taken into consideration.

### ***Specification***

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not have support to a content of less than 2% of 8,10-octadecadienoic acid and 11,13 octadecadienoic acid isomers.

***Claim Rejections - 35 USC § 112***

4. Claim 12 recites the limitation "less than 2% in the aggregate" in line 7. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by J.L. Sebedio et al. Geometry of conjugated double bonds of CLA isomers in a commercial mixture and in their hepatic 20:4 metabolites, *Lipids*, Volume 34, Number 12 / December, 1999, pages 1319-1325. (provided in the IDS dated 2/15/07)

Sebedio teaches a mixture of conjugated linoleic acids (CLA) as triacylglycerols. Infrared analyses of the resulting monoenes, revealed the presence of two major isomers, the 9*c*, 11*t*- and the 10*t*, 12*c*-18:2 of an amount over 50% and accompanied by smaller amounts of the 8*t*, 10*c* and the 11*c*, 13*t*-18:2 isomers (abstract). The reference teaches that a minor elution has been detected of 8,11 of 0.2% and 11,13 of 0.6%. accordingly, the percentage of the two isomers is less than 2% (page 1320, col. 2).

***Conclusion: claims 12 and 13 are anticipated by Sebedio.***

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

a. **Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Saebo Asgier et al. US 6015833 (Saebo) or Saebo et al. US 7029691 (Saebo1).**

Saebo teaches novel compositions containing conjugated linoleic acids are efficacious as animal feed additives and human dietary supplements. Linoleic acid is converted to its conjugated forms in which the resulting composition is low in certain unusual isomers compared to conventional conjugated linoleic products. the linoleic acid composition containing at least 50 percent conjugated linoleic acid said isomerized linoleic acid composition being characterized in having less than 1 percent of a class of

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octadecadienoic acid isomers selected from 11,13-octadecadienoic acid isomers, 8,10-octadecadienoic acid isomers and trans-trans octadecadienoic acid isomers (see claims).

Saebo 1 teaches a biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R.sub.1, R.sub.2, and R.sub.3 attached at the positions of the OH-- groups of a glycerol backbone, and wherein R.sub.1, R.sub.2, and R.sub.3 are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans—trans octadecadienoic acid at positions R.sub.1, R.sub.2, and R.sub.3

The references do not teach the exact percentage of less than 2% of 11,13-octadecadienoic acid isomers, 8,10-octadecadienoic acids.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the linoleic acids composition containing an amount of octadecadienoic acid isomers selected from 11,13-octadecadienoic acid isomers, 8,10-octadecadienoic acid isomers and trans-trans octadecadienoic of less than 2% because the 1% claimed by Saebo is within the range of less than 2% recited in instant claim 12. The expected result would be triglyceride rich in conjugated linoleic acid and containing less than 2% of 11,13-octadecadienoic acid isomers, 8,10-octadecadienoic acids.

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b. **Claim 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cain WO 9718320 (Cain) in view of R.O. Adlof et al., Changes in Conjugated Linoleic acid Composition Within Samples Obtained from a Single Source, Lipids, Vol. 36, no. 3, 2001, pages 315-317 (Adlof) .**

Cain teaches an acylglyceride mixture comprising at least one C18:2 fatty acid moiety selected from the group consisting of c9,t11 octadecadienoic acid (linolic acid), wherein said mixture has a c9,t11 octadecadienoic acid content of greater than 50%, see examples, especially example 6. the triglyceride mixtures would have the same formula as claimed, see abstract and example 6.

The reference does not teach percentage of less than 2% of 11,13-octadecadienoic acid isomers, 8,10-octadecadienoic acids.

Adlof teaches that data from animal models have been used to suggest the 9c,11t-isomer is responsible for CLA's anticarcinogenic properties, whereas the 10t,12c-isomer is considered responsible for the observed weight loss/muscle-mass enhancement effects (12,13). The different CLA isomers present in commercially available diet supplements may thus have different health-related benefits, and other isomers ((11c,13t-18:2, for example) may potentially be harmful (page 315).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to lower the percentage of 11,13-octadecadienoic acid isomers 8,10-octadecadienoic acids as low as possible in a mixture of CLA because the skilled artisan would be aware of the harmful isomers and would try to avoid it. The expected results would be an acylglyceride mixture comprising at least one C18:2 fatty acid

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moiety selected from the group consisting of c9,t11 octadecadienoic acid (linolic acid), wherein said mixture has a c9,t11 octadecadienoic acid content of greater than 50% while the percentage of 11,13-octadecadienoic acid isomers 8,10-octadecadienoic acids is as low as possible in the human or animal consumed compositions.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 12, and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7029691.

Although the conflicting claims are not identical, they are not patentably distinct from each other because '691 claims biologically active acylglycerol composition comprising acylglycerol molecules wherein the acylglycerol molecules comprise substituents

R.sub.1, R.sub.2, and R.sub.3 attached at the positions of the OH—groups of a glycerol



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backbone, and wherein R.sub.1, R.sub.2, and R.sub.3 are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition, characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans—trans octadecadienoic acid at positions R.sub.1, R.sub.2, and R.sub.3. The molecules of the compound recited in '691 is the same as the compounds recited in the instant application and in the same ranges of amounts except for the amounts of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans—trans octadecadienoic acid which would have been obvious to one of ordinary skill in the art to prepare the same compounds having less than 2% of the 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans—trans octadecadienoic acid.

### ***Other Matters***

Applicant submitted a decision of the Board of Appeal for application 09/438104. it is noted that the application is not a parent of the instant application, however, the decision was considered and Applicant's arguments related to it renders moot in view of the new grounds of rejection.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

  
MICHAEL G. HARTLE  
SUPERVISORY PATENT EXAMINER